ITM Announces FDA Acceptance of New Drug Application (NDA) and PDUFA Date for n.c.a. ^{177}Lu-edotreotide (ITM-11) in Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)

- Prescription Drug User Fee Act (PDUFA) goal date set for August 28, 2026

Garching / Munich, Germany, November 13, 2025 – ITM Isotope Technologies Munich SE (ITM), a leading radiopharmaceutical biotech company, today announced that the U.S. Food and Drug Administration (FDA) completed its filing review and accepted the company's New Drug Application (NDA) for n.c.a. ^{177}Lu-edotreotide (also known as ITM-11 or ^{177}Lu-edotreotide). ^{177}Lu-edotreotide is ITM's proprietary, synthetic, targeted radiotherapeutic investigational agent for the treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs). The FDA has set a Prescription Drug User Fee Act (PDUFA) goal date of August 28, 2026.

"The FDA's acceptance of our NDA is an important regulatory milestone in advancing this new radiopharmaceutical treatment option for patients with GEP-NETs," said **Dr. Celine Wilke, chief medical officer of ITM**. "In the Phase 3 COMPETE trial, ^{177}Lu-edotreotide demonstrated extended PFS, a straightforward dosing regimen, and a favorable safety profile, supporting its potential to improve the current treatment paradigm. We look forward to working closely with the FDA toward potential approval."

The NDA submission for ^{177}Lu-edotreotide is supported by results from the Phase 3 COMPETE study, a prospective, randomized, controlled, open-label trial that enrolled 309 patients with inoperable, progressive Grade 1 or Grade 2 GEP-NETs as a first- or second-line treatment. The trial met its primary endpoint, revealing a significantly longer median mPFS in patients treated with agent ^{177}Lu-edotreotide compared to everolimus, a targeted molecular therapy. Patients treated with ^{177}Lu-edotreotide also demonstrated a significantly higher ORR compared to everolimus.

"This milestone reflects more than 20 years of leadership and dedication to advancing the radiopharmaceutical field, built on our global isotope manufacturing, clinical expertise, and pipeline of targeted therapeutics and diagnostics," said **Dr. Andrew Cavey, chief executive officer of ITM**. "Above all, we are driven by a single focus: making a real difference for people living with hard-to-treat cancers."

About the COMPETE Trial

The COMPETE trial (NCT03049189) evaluated ^{177}Lu-edotreotide (ITM-11), a proprietary, synthetic, targeted radiotherapeutic investigational agent compared to everolimus, a targeted molecular therapy, in patients with inoperable, progressive Grade 1 or Grade 2 gastroenteropancreatic neuroendocrine tumors (GEP-NETs). This trial met its primary endpoint, with ^{177}Lu-edotreotide demonstrating clinically and statistically significant improvement in progression-free survival (PFS) compared to everolimus. ^{177}Lu-edotreotide is also being evaluated in COMPOSE, a Phase 3 study in patients with well-differentiated, aggressive Grade 2 or Grade 3, SSTR-positive GEP-NET tumors.

About ITM Isotope Technologies Munich SE

ITM, a leading radiopharmaceutical biotech company, is dedicated to providing a new generation of radiopharmaceutical therapeutics and diagnostics for hard-to-treat tumors. We aim to meet the needs of cancer patients, clinicians, and our partners through excellence in development, production, and global supply of medical radioisotopes. With improved patient benefit as the driving principle for all we do, ITM advances a broad precision oncology pipeline, including multiple phase 3 studies, combining the company's high-quality radioisotopes with a range of targeting molecules. By leveraging our two decades of pioneering radiopharma expertise, central industry position and established global network, ITM strives to provide patients with more effective targeted treatment to improve clinical outcome and quality of life. www.itm-radiopharma.com

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